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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

JOHN DUNNE, III,	:	
	:	
Plaintiff,	:	Civil Action No.: 2:21-cv-19947
	:	
vs.	:	
	:	
KAMRAN TASHAROFI, INDIVIDUALLY,	:	
UNION COUNTY HEALTH CARE	:	
ASSOCIATES A/K/A UCHA; JOSE	:	
POLANCO, INDIVIDUALLY, JOHN DOE	:	
1-10 AND ABC CORPORATION 1-10 (THE	:	
LAST TWO NAMES BEING UNKNOWN	:	
AND FICTITIOUS),	:	
	:	
Defendants.	:	
	:	

**DEFENDANTS' BRIEF IN OPPOSITION
TO PLAINTIFF'S MOTION TO REMAND**

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PRELIMINARY STATEMENT

The PREP Act’s language easily satisfies the standard for complete preemption of particular causes of action.... Congress said the cause of action for willful misconduct is exclusive, so it is.

Estate of Maglioli v. Alliance HC Holdings LLC, 16 F.4th 393, 409-10 (3rd Cir. 2021).

* * *

The Public Readiness and Emergency Preparedness Act of 2005, 42 U.S.C. §§ 247d-6d, 247d-6e (the “PREP Act”), expressly provides an exclusive federal cause of action for covered claims alleging willful misconduct, and Congress has directed that this exclusive federal cause of action must be brought in the United States District Court for the District of Columbia. The Third Circuit Court of Appeals—the only federal appellate court thus far to address this issue—recently held that, because the PREP Act creates an exclusive federal cause of action for claims of willful misconduct covered by the PREP Act, it completely preempts state law for purposes of those claims and justifies removal to federal court, and Congress could not have been clearer on that point. *See Maglioli, supra*, 16 F.4th at 407-10. Other federal courts have agreed.

When state law is completely preempted, federal question jurisdiction is properly invoked, as is the case here. *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 65 (1987). Plaintiff’s claims are the quintessential example of claims that are completely preempted under the PREP Act: Plaintiff alleges that Defendants engaged in willful misconduct by deliberately and improperly administering a COVID-19 diagnostic test to him, leading to a false and inaccurate test result. Plaintiff’s claims must therefore be heard in federal court.

Plaintiff wholly misses the crucial purpose of the PREP Act and its exclusive federal cause of action for willful misconduct claims. Plaintiff cites a host of factually and legally inapposite authority – none of which analyzes the PREP Act. Furthermore, not one of the cases cited by

Plaintiff in his brief involve **willful misconduct** claims covered by the PREP Act. Because Plaintiff in this case alleges willful misconduct, the PREP Act provides the exclusive federal cause of action for his claims and completely preempts state law for purposes of those claims. Accordingly, Plaintiff's asserted state-law claims invoke federal jurisdiction, making removal to this Court proper. Plaintiff's Motion for Remand must be denied.

RELEVANT FACTS AND PROCEDURAL HISTORY

A. The PREP Act

Congress enacted the PREP Act in the wake of the 2003 SARS outbreak to provide certain protections to health-care providers fighting on the front lines of future public health emergencies. The PREP Act provides immunity from liability for certain "covered persons" related to the manufacture, testing, development, distribution, administration, and use of medical countermeasures with regard to diseases, threats, and conditions declared by the Secretary of Health and Human Services (HHS) to constitute a public health emergency.

Specifically, the Act provides that "a covered person shall be immune from suit and liability under Federal and State law with respect to **all** claims for loss caused by, arising out of, **relating to**, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration . . . has been issued with respect to such countermeasure." 42 U.S.C. § 247d-6d (emphasis added). The immunity "applies to any claim for loss that has **a** causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." *Id.* at

§ 247d-6d(a)(2)(B)(emphasis added). Any state law that “is different from, or in conflict with, any requirement applicable [for immunity]” is expressly preempted. 42 U.S.C. § 247d-6d(b)(8).

“The sole exception to the immunity from suit and liability of covered persons” is “for death or serious physical injury proximately caused by willful misconduct. . . .” 42 U.S.C. § 247d-6d(d)(1).¹ In the case of willful misconduct, the exclusive remedy is a federal cause of action that must be “filed and maintained **only** in the United States District Court for the District of Columbia.” *Id.* at § 247d-6d(e)(1)(emphasis added). Not only did Congress set out in the PREP Act exclusive Federal Jurisdiction in the United States District Court for the District of Columbia, but it also detailed a comprehensive scheme for the litigation of these permissible claims. *See id.* at §§ 247d-6d(a)(2) (scope and accrual of claims for loss), (c)(1) (liability standard of willful misconduct), (c)(3) (burden of proof), (e)(2) (choice of law provision), (e)(3) (pleading standard of particularity), (e)(4) (pleading requirements of verification and certain materials), (e)(5) (congressional creation of a “three-judge court” in the D.D.C. and direct appeal to Supreme Court from injunction orders), (e)(6) (motions practice and discovery process), (e)(7) (parameters for recoverable damages), (e)(8) (noneconomic damages allowed), (e)(9) (Rule 11 sanctions), (e)(10) (interlocutory appeal process in the United States Court of Appeals for the District of Columbia Circuit).

In addition to the exclusive federal litigation scheme for willful misconduct claims, 42 USC § 247d-6e establishes a no-fault fund, called Countermeasure Injury Compensation Program. This fund permits claimants to seek relief for their injuries from the administration of covered countermeasures to them. This fund permits recovery for claims for which the claimant cannot

¹ The PREP Act defines “willful misconduct” as (1) “an act or omission,” that is taken (2) “intentionally to achieve a wrongful purpose,” (3) “knowingly without legal or factual justification,” and (4) “in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.” 42 U.S.C. § 247d-6d(c)(1)(A).

otherwise file suit due to PREP Act’s immunity from suit provision, or for which they may later choose to file a willful misconduct lawsuit in the United States District Court for the District of Columbia if they are dissatisfied with the award they receive.²

On February 4, 2020, the Secretary of Health and Human Services issued a declaration under the PREP Act declaring COVID-19 to be a public health emergency (the “Declaration”).³ *See* 85 Fed. Reg. 15198 (Mar. 10, 2020). The Declaration triggers the PREP Act’s immunity provisions, which extend through either (1) the final day the emergency Declaration is in effect, or (2) October 1, 2024, whichever occurs first. “Covered countermeasures” under this Declaration include “any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.” *Id.* at 15202. The definition applies to COVID-19 diagnostic tests. *See id.*; EUA, U.S. Food & Drug Admin.,

² This streamlined, publicly-funded no-fault administrative process provides an efficient remedy for claimants, and it is also a predicate for any willful misconduct suit that is ultimately filed in the Federal Court. *See id.* at §§ 247d-6e(a) (Covered Countermeasure Process Fund (“CCPF”) for “purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries”), (d)(1) (requires exhaustion of administrative process prior to pursuing litigation in D.D.C.), (d)(2) (tolling of statute of limitations), (d)(4) (“exclusivity” of federal administrative remedy except for “willful misconduct” litigation in D.D.C.), (d)(5) (election to accept administrative compensation or proceed to litigation claim in D.D.C.); *see also* 42 C.F.R. §§ 110.1-110.100 (regulations related to administrative claims process).

³ To date, the Declaration has been amended nine (9) times, five (5) of which have been under the Biden Administration, further confirming the expansive breadth of the Act and its immunity and preemptive effect. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (“Declaration”), 85 Fed. Reg. 15198 (Mar. 10, 2020), *amended by* 85 Fed. Reg. 21012 (Apr. 15, 2020), 85 Fed. Reg. 35100 (June 8, 2020), 85 Fed. Reg. 52136 (Aug. 24, 2020), 85 Fed. Reg. 79190 (Dec. 9, 2020), 86 Fed. Reg. 7872 (February 2, 2021), 86 Fed. Reg. 9516 (February 16, 2021), 86 Fed. Reg. 14462 (Mar. 16, 2021), 86 Fed. Reg. 41977 (Aug. 4, 2021), and 86 Fed. Reg. 51160 (Sept. 14, 2021) (*as corrected by* 86 Fed. Reg. 54696 (Oct. 4, 2021)). In its May 19, 2020 Advisory Opinion, HHS reiterated: “PREP Act immunity must be read in light of the PREP Act’s broad, express-preemption provision.” *See* Advisory Opinion 20-01 on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, p. 2 (May 19, 2020); *see also* 85 Fed. Reg. at 79194, 79197; 86 Fed. Reg. 7872, 7874 (Feb. 2, 2021).

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidppe>.

The Secretary also defined “administration of a covered countermeasure” in the Declaration as the “physical provision of the countermeasures to recipients or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.” *See* 85 Fed. Reg. 15200 (Mar. 10, 2020). Accordingly, the broad definition of “administration” of covered countermeasures encompasses not only the use of countermeasures but also decisions with respect to the use of countermeasures, such as COVID-19 testing kits. Furthermore, “administration” also includes “activities. . .directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs. . . .” *Id.* at 15202.

Notably, Congress directed that “[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under [the PREP Act].” 42 U.S.C. § 247d-6d(7). Thus, the Secretary’s Declaration (including all amendments thereto) – including his definition of the term “administration” which is not defined in PREP Act itself but only in the Secretary’s Declaration - is controlling by express delegation of Congress and not subject to review by any court.⁴ And the Third Circuit in *Maglioli*

⁴ Section (b) of the PREP Act provides that if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, the Secretary may make a declaration setting forth that subsection (a) is in effect with respect to one or more covered countermeasures **under conditions as the Secretary may specify in the Declaration**. 42 U.S.C. § 247d-6d(b)(1). Also, when Congress delegates such authority to an agency to generally make rules *carrying the force of law*, that agency’s interpretation in the exercise of that authority is entitled to deference. *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). Indeed, the court in *Garcia v. Welltower OpCo Group LLC*, 522 F.Supp.3d 734, 742, 745 (C.D. Cal. Feb. 10, 2021), reasoned that deference is indeed owed to HHS in interpreting the PREP Act given its “specialized experience,” the broader

recently confirmed that the Secretary of HHS has broad and extensive non-reviewable authority bestowed on him by Congress for all substantive applications of the PREP Act as “the Secretary controls the scope of immunity through the declaration and amendments” including defining what “acts and omissions” fall under the Act. *Maglioli, supra*, 16 F.4th at 401.

B. Plaintiff’s Claims.

Plaintiff’s Complaint alleges that defendant Kamran Tasharofi, MD is a medical doctor and employee of defendant Union County Health Care Associates, LLC. *See* ECF 1, Exhibit A, Compl. ¶¶ 2, 9. Plaintiff alleges that defendant Jose Polanco, APN is an employee of Union County Health Care Associates, LLC. *See id.* at ¶ 4. Plaintiff also claims that defendant Union County Health Care Associates, LLC is a business and employer for the individual defendants at all times relevant to the complained-of actions. *See id.* at ¶¶ 3-4.

Plaintiff’s claims relate to and arise from the administration of a COVID-19 test to him during the early part of the pandemic by Defendants Kamran Tasharofi, MD, Jose Polanco, APN, and Union County Health Care Associates, LLC (collectively “Defendants”). *See id.* at ¶¶ 10-12, 20. Specifically, Plaintiff claims Defendants improperly administered the COVID-19 test to him, leading to a false and inaccurate result (false positive). He claims that he actually did not have the virus. *See id.* at ¶ 20. Plaintiff further pleads that Defendants thereafter wrongfully disclosed

information available to the agency, and the “value of uniformity in its administrative and judicial understandings of what a national law requires.” Like *Garcia*, another district court in *Rachal* also concluded that “HHS’s interpretation of the PREP Act and its scope is reasonable” and likewise warrants deference given: “(i) the PREP Act’s broad grant of authority to the HHS Secretary; (ii) the Secretary’s express incorporation of the OCC’s AOs into the Declarations for purposes of construing the PREP Act; (iii) the complexity of the relevant statutory provisions; (iv) the technical nature of the subject matter; and (v) the need for uniformity in the judiciary’s interpretation of the PREP Act across the United States.” *See Rachal v. Natchitoches Nursing & Rehab. Ctr. LLC*, No. 1:21-cv-334, 2021 U.S. Dist. LEXIS 105847, at *13 (W.D. La. Apr. 30, 2021). HHS’s interpretation of the PREP Act in its implementing Declaration, its recent Amendments, and its several Advisory Opinions, is entirely consistent with the purpose and scope of the Act as well as with all HHS’s proclamations to date (including those made by HHS under the Biden Administration) in invoking and applying the PREP Act broadly in this unprecedented COVID-19 pandemic, thereby entitling HHS’s directives and opinions to appropriate controlling deference by virtue of Congressional directive as well as under Supreme Court precedent.

inaccurate COVID-19 test results to third parties. *See id.* at ¶¶ 11-13, 15-19, 21. Plaintiff claims that Defendants’ conduct was willful, wanton, reckless, negligent, and careless, causing him to sustain personal injuries and other damages, including his termination from employment. *See id.* at ¶¶ 9, 21, 23-30. Plaintiff alleges, *inter alia*, that Defendants willfully and intentionally inflicted permanent emotional distress upon Plaintiff that is so severe that no reasonable person could be expected to endure it. *See id.* at ¶¶ 23-30.

Plaintiff filed his complaint in the Superior Court of New Jersey, Union County and all Defendants *together* timely removed the action to this Court pursuant to 28 U.S.C. §§ 1331 and 42 U.S.C. §§ 247d-6d, 247d-6e. All Defendants have therefore necessarily joined and consented to the removal.

LEGAL ARGUMENT

I. FEDERAL QUESTION JURISDICTION EXISTS BY VIRTUE OF COMPLETE PREEMPTION UNDER THE PREP ACT

Under 28 U.S.C. § 1441, a defendant may remove a civil action from state court to federal district court if “the district courts of the United States have original jurisdiction” over the case. *See Chicago v. Int’l Coll. of Surgeons*, 522 U.S. 156, 163 (1997) (“The propriety of removal thus depends on whether the case originally could have been filed in federal court.”).

A. Plaintiff’s Claims Are Covered by the PREP Act.

A plaintiff’s claim for loss falls within the scope of the PREP Act if it was caused by “a covered person” and “aris[es] out of, relat[es] to, or result[s] from the administration to or the use by an individual of a covered countermeasure.” *See* 42 U.S.C. § 247d-6d(a)(1). Here, it is evident on the face of the Complaint, that Defendants are “covered persons,” and that Plaintiff’s claims relate to the administration and use of a “covered countermeasure”—specifically, a COVID-19 diagnostic test.

1. Defendants Are Covered Persons.

Plaintiff ostensibly does not dispute that Defendants are “covered persons” under the PREP Act, for he does not make any argument to the contrary. “Covered persons” broadly include individuals as well as private and public entities. *See Garcia v. Welltower OpCo Grp. LLC*, 522 F. Supp. 3d 734, 744 (C.D. Cal. 2021) (citing Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration under the Act, p. 2-3 (October 23, 2020)). The term “person” is defined broadly and “includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.” 42 U.S.C. § 247d-6d(i)(5). A “covered person” under the Act includes:

(A) the United States; or (B) a person or entity that is (i) a manufacturer of [a covered] countermeasure; (ii) a distributor of such countermeasure; (iii) a program planner of such countermeasure; (iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or (v) an official, agent, or employee of a person or entity described in clauses (i), (ii), (iii), or (iv).

Id. at § 247d-6d(i)(2). The term “program planner” means:

a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration [issued by the Secretary].

Id. at § 247d-6d(i)(6).

A “qualified person” is defined as “a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State

in which the countermeasure was prescribed, administered, or dispensed.” *Id.* at § 247d-6d(i)(2)(B)(iv). The Declaration explains that “qualified persons” include:

Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency; (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act; and (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

Declaration, 85 Fed. Reg. at 15201-15202 (March 17, 2020).⁵

Indeed, the Third Circuit in *Maglioli* recently stated that a “covered person” under the PREP Act enjoys immunity from all claims arising under federal or state law that relate to the use and administration of a covered countermeasure. *Maglioli, supra*, 16 F.4th at 401; *see* 42 U.S.C. § 247d-6d(a)(1). Courts have further concluded that the PREP Act “exclusively encompass[es]” claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use or misuse by an individual of a covered countermeasure and that such claims will be precluded under the PREP Act. *See Rachal v. Natchitoches Nursing & Rehab. Ctr. LLC*, No. 1:21-cv-334, 2021 U.S. Dist. LEXIS 105847, at *4 n.3 (W.D. La. Apr. 30, 2021); *see Garcia, supra*, 522 F. Supp. 3d at 740; *see also Branch v. Lilac Holdings, LLC*, No. 21-cv-00605-BAS-MDD, 2021 U.S. Dist. LEXIS 113068 (S.D. Cal. June 16, 2021) (granting defendants’ motion to dismiss based on

⁵ The Declaration further defined “Authority Having Jurisdiction” as the “public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range of sphere or authority.” 85 Fed. Reg. at 15202.

immunities within the PREP Act); *Reilly v. Delta Healthcare II, LLC*, No. 8:21-cv-1013-JSM-JSS (M.D. Fla June 7, 2021).

Here, it is evident on the face of Plaintiff’s Complaint that Defendants are “covered persons” under the PREP Act, and Plaintiff does not make any argument to the contrary. Plaintiff alleges that Defendants operated and managed a COVID-19 testing site and that Defendants administered and used covered countermeasures, *i.e.*, a COVID-19 diagnostic test, to mitigate the spread of COVID-19. *See* EFC 1, Compl. ¶¶ 2-4, 11-13, 20, 27. Dr. Tasharofi is a physician licensed to practice medicine in the State of New Jersey. Dr. Tasharofi was a “qualified person” during the relevant time period, as he was a licensed physician authorized to prescribe, administer or dispense covered countermeasures, including COVID-19 diagnostic countermeasures, such as COVID-19 tests. APN Polanco is an advanced practice nurse licensed to practice in the State of New Jersey. APN Polanco was acting as a “qualified person” during the relevant time period, as he was a licensed advanced practice nurse authorized to administer or dispense covered countermeasures, including COVID-19 diagnostic countermeasures, such as COVID-19 tests. Plaintiff also alleges that Defendants provided “medical services to Plaintiff in April 2020” and administered the COVID-19 diagnostic test covered countermeasure to the Plaintiff. *See id.* at ¶ 20. Dr. Tasharofi and Union County Health Care Associates were also acting as “program planners” in that they were responsible for administering and supervising a program related to the dispensing of a covered countermeasure to Plaintiff and other patients – specifically, the administration of a diagnostic test for COVID-19.⁶ Therefore, Defendants are clearly “covered persons” under the PREP Act.

⁶ The Secretary’s Declaration specifies that a community group, private sector employee “or other ‘person’ can be a program planner when it carries out the described activities.” 85 Fed. Reg. at 15199. On January 8, 2021, the Office of the Secretary of HHS affirmatively stated in Advisory Opinion 21-01 that: “A program planner is someone who is

2. Plaintiffs' Claims Relate to the Administration and Use of Covered Countermeasures.

Plaintiff's claims are covered by the PREP Act because, on their face, they relate to Defendants' administration and use of a covered countermeasure – that is, a COVID-19 diagnostic test. The PREP Act applies to “all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” 42 U.S.C. § 247d-6d(a)(1). As explained above, “covered countermeasures” include “any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.” 85 Fed. Reg. 15,202; *see* First Amended Declaration, 85 Fed. Reg. at 21013-14. To date, a large number of diagnostic tests for use in detecting or preventing the spread of COVID-19 have been approved, licensed, or cleared by the FDA, or are subject to an EUA.⁷ HHS retroactively “extended PREP Act coverage to licensed health-care practitioners prescribing or administering FDA-authorized COVID-19 tests” in October 2020,⁸ and even confirmed that PREP Act coverage extends even to “off-label (outside the authorization) use.”⁹

involved in providing or allocating covered countermeasures. Program planning inherently involves the allocation of resources and when those resources are scarce, some individuals are going to be denied access to them. Therefore, decision-making that leads to the non-use of covered countermeasures by certain individuals is the gist of program planning, and is expressly covered by PREP Act[.]” *See* Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, p. 4 (January 8, 2021).

⁷ *See* FDA, FDA Combatting COVID-19 with Medical Devices, <https://www.fda.gov/media/136702/download>.

⁸ *Letter from the Secretary of HHS*, dated August 31, 2020, <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf>.

⁹ *Id.*

Moreover, the PREP Act applies to use, administration, misuse and non-use of a covered countermeasure. Fourth Amendment, 85 Fed. Reg. 79190, 79197. HHS has confirmed time and again that “administration” under the PREP Act encompasses activities related to “management and operation” of COVID-19 countermeasure programs and those facilities that provide countermeasures to recipients. *See* Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration under the Act, p. 6-7 (October 23, 2020). “[D]ecision-making” related covered countermeasures “is expressly covered by the PREP Act.” *See* Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration under the Act, p. 4 (January 8, 2021).¹⁰ And notably, test reporting is part of the administration of the COVID-19 diagnostic test, because it is part of the “management and operation of the countermeasure program” and involves “activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures” to mitigate the spread of COVID-19. *See* Declaration, 85 Fed. Reg. at 15,202. Reporting is a necessary component to diagnostic testing. *See* HHS, “COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115,” January 8, 2021, <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>.

Additionally, even if Plaintiff alleges other actions as contributing to his injuries, the PREP Act’s coverage provisions do not require that the use or administration of a covered countermeasure be the exclusive cause of injury or death. Rather, it merely requires that the

¹⁰ The Fourth Amendment to the Declaration expressly incorporated the Advisory Opinions into the Declaration of the PREP Act and directed that “the Declaration *must be construed in accordance with the Advisory Opinions*.” 85 Fed. Reg. 79192 (emphasis added). All subsequent Amendments issued to date under the Biden Administration have also reiterated this provision of the Fourth Amendment to the Declaration. *See, e.g.*, 85 Fed. Reg. 7872 (Feb. 2, 2021); 86 Fed. Reg. 9516 (Feb. 16, 2021); 86 Fed. Reg. 14462 (Mar. 16, 2021); 86 Fed. Reg. 41977 (Aug. 4, 2021); 86 Fed. Reg. 51160 (Sept. 14, 2021). Thus, the Advisory Opinions that are now incorporated therein now carry that same weight. *See* 42 U.S.C. § 247d-6d(7) (“No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under [the PREP Act].”)

Plaintiff's claims for loss "relate to" the administration or use of a covered countermeasure. There can be no doubt on the face of Plaintiff's Complaint that his claims relate to the alleged improper administration of a COVID-19 diagnostic test. *See* EFC 1, Compl. ¶¶ 10-13, 20, 27-30. Accordingly, Plaintiff's claims relate to the administration and use of covered countermeasures and are covered by the PREP Act.

B. The PREP Act Completely Preempts Plaintiff's Claims.

This Court has federal question jurisdiction over this case because the PREP Act completely preempts, displaces, and provides a substitute cause of action for Plaintiff's state-law claims. Plaintiff alleges willful misconduct, and the Third Circuit has confirmed that the PREP Act "unambiguously" and "explicitly" provides an exclusive federal cause of action and exclusive jurisdiction in the U.S. District Court for the District of Columbia for this claim alleging willful misconduct. *Maglioli, supra*, 16 F.4th at 409-10. As such, this action was properly removed to federal court. *Id.*

Generally, under the well-pleaded complaint rule, federal jurisdiction exists only when a federal question is presented on the face of a complaint. *Gully v. First National Bank*, 299 U.S. 109, 112-113 (1936). However, federal question jurisdiction may exist as a result of the "complete [or artful] preemption doctrine," which applies where the preemptive force of a statute "converts an ordinary state common-law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule." *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 65 (1987). Under the "complete preemption" doctrine, claims pleaded under state law are removable to federal court where a federal statute has such "unusually powerful preemptive force" that the claims are deemed

to arise under federal law.¹¹ *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 7 (2003). Complete preemption is “really a jurisdictional rather than a preemption doctrine,” as it confers federal jurisdiction where Congress intended “to entirely replace any state-law claim.” *Franciscan Skemp Healthcare, Inc. v. Cent. States Joint Bd. Health & Welfare Trust Fund*, 538 F.3d 594, 596 (7th Cir. 2008). Where a federal statute provides an exclusive cause of action for the asserted state-law claim, courts have found that it is completely preemptive and thereby gives rise to original federal jurisdiction, allowing for removal under 28 U.S.C. § 1441. *See Anderson, supra*, 539 U.S. at 9.

The Supreme Court of the United States has recognized the doctrine of complete preemption as a basis for federal question removal jurisdiction under 28 U.S.C. § 1441(a) in several different contexts. *See Avco Corp. v. Aero Lodge No. 735, Intern. Ass’n of Machinists and Aerospace Workers*, 390 U.S. 557, 559 (1968) (holding that the Labor Management Relations Act, 1947 completely preempted state court jurisdiction); *Taylor, supra*, 481 U.S. 58; *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004) (ERISA completely preempts state law); *Anderson*, 539 U.S. at 7-11 (National Bank Act completely preempts); *see also In re WTC Disaster Site*, 414 F.3d 352, 375 (2nd Cir. 2005) (Air Transportation Safety and System Stability Act completely preempted state claims and ousted state courts of jurisdiction by creating an exclusive federal cause of action). “Once an area of state law has been completely pre-empted, any claim purportedly based on that pre-empted state-law claim is considered, from its inception, a federal claim, and therefore arises under federal law.” *Rivet v. Regions Bank of Louisiana*, 522 U.S. 470, 472 (1998).

¹¹ Therefore, Plaintiff’s argument that his Complaint does not cite a federal question is unavailing, as complete preemption is an exception to the well-pleaded complaint rule. Plaintiff therefore cannot avoid litigating this case in federal court merely by omitting reference to the express federal cause of action under the PREP Act for his willful misconduct claim. *See Koresko v. Murphy*, 464 F. Supp. 2d 463, 469 (E.D. Pa. 2006). Moreover, removal pursuant to federal-question jurisdiction does not require that a plaintiff’s complaint exclusively contain federal questions, but merely that it raise at least one federal question. “The presence of one federal question is enough to support removal of the entire action.” *Prachun v. CBIZ Benefits & Ins. Servs.*, S.D. Ohio No. 2:14-cv-2251, 2015 U.S. Dist. LEXIS 12470, at *5 (Feb. 3, 2015).

The Third Circuit in *Maglioli* is the only federal appellate court thus far to consider removal jurisdiction pursuant to the PREP Act, and it has confirmed that PREP Act completely preempts willful misconduct claims that fall thereunder, making them removable to federal court because “the PREP Act creates an exclusive cause of action for willful misconduct.” *Id.* The Court explained:

The PREP Act’s language easily satisfies the standard for complete preemption of particular causes of action. It provides an “exclusive cause of action . . . and also set[s] forth procedures and remedies governing that cause of action.” *Beneficial Nat’l Bank*, 539 U.S. at 8. . . . The Supreme Court has relied on the complete preemptive force of a statute to infer congressional intent to create an exclusive federal cause of action. Here, we have a better source of congressional intent: the words of Congress. Again, our analysis is straightforward. Congress said the cause of action for willful misconduct is exclusive, so it is.

Maglioli, supra, 16 F.4th at 401 (emphasis added).¹²

Here, Plaintiff alleges willful misconduct in connection with Defendants’ administration and use of a covered countermeasure. The Complaint alleges that Defendants willfully and intentionally administered the COVID-19 diagnostic test to him incorrectly and willfully disclosed false and inaccurate testing results – all to achieve a wrongful purpose without any factual or legal justification. *See* EFC 1, Exhibit A, Compl. ¶¶ 10-13, 23-30. Plaintiff further claims that, in doing so, Defendants willfully and intentionally inflicted permanent emotional distress on him that is so severe that no reasonable person could be expected to endure it. *See ibid.* Clearly, Plaintiff alleges facts that arise out of and relate to the administration and use of a COVID-19 diagnostic test, i.e., a covered countermeasure, and the facts squarely satisfy the elements of PREP Act willful misconduct. *See* 42 U.S.C. § 247d-6d(c)(1)(A). The PREP Act therefore provides an exclusive

¹² Other courts have come to the same conclusion. A very recent opinion from the District Court of South Carolina similarly recognized that the PREP Act is a complete preemption statute for certain claims. *Dozier v. Carlyle Senior Care of Kingstree, LLC*, No. 4:21-cv-01303-SAL (D.S.C. November 30, 2021).

federal cause of action for Plaintiff's claims, giving rise to original federal jurisdiction, and as a consequence allows removal under 28 U.S.C. § 1441.

To the extent that the pleadings assert any non-willful claims, they are subject to the Court's supplemental jurisdiction under 28 U.S.C. §1367 because they are "so related to [the willful misconduct] claims . . . that they form part of the same case or controversy." Moreover, as long as one claim triggers complete preemption, there is federal jurisdiction over the entire suit. *Smallwood v. Allied Van Lines, Inc.*, 660 F.3d 1115, 1120 (9th Cir. 2011) ("district court had subject matter jurisdiction if at least one of [plaintiff's] claims were completely preempted"); see also *Giles v. NYL Care Health Plans, Inc.*, 172 F.3d 332, 337-38 (5th Cir. 1999).

As such, under the Third Circuit reasoning in *Maglioli*, the claims here were properly removed to federal court.¹³

II. THE GRABLE DOCTRINE PROVIDES AN INDEPENDENT BASIS FOR FEDERAL JURISDICTION.

Plaintiff wrongly argues that the doctrine articulated in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), granting federal question jurisdiction over federal issues embedded in state law claims, should not be applied here. The facts

¹³ Unlike Plaintiff in this case, the plaintiffs in *Maglioli* did not allege any claims of willful misconduct, and the Court affirmed remand. *Maglioli, supra*, 16 F.4th at 410. However, *Maglioli* is not final in this regard as appellants have sought a rehearing en banc from the Third Circuit as to same. Indeed, and although not necessarily relevant here, the complete preemptive force of the PREP Act is not limited solely to willful misconduct as such a narrow finding would eviscerate the broad purposes of the PREP Act to provide a unified, rapid federal response to a national public health threat, and to prevent covered persons from being distracted by the cost and conflicting standards of litigation in multiple forums. Declaration, 85 Fed.Reg. 15195. Defendants therefore maintain that the PREP Act is a complete preemption statute as to all claims regardless of whether the standard is one of willfulness or negligence. Importantly, "willful misconduct" is not the cause of action, it is a component part of the PREP Act federal cause of action. 42 U.S.C. §247d-6d(c); *contra Maglioli, supra*, 16 F.4th at 407-08. The "willful misconduct" requirement is a "standard of liability." §247d-6d(c)(1)(B). Accordingly, the PREP Act creates a civil federal cause of action for a "person who suffered an injury" relating to a COVID-19 countermeasure, program, or facility, at the hands of a "covered person." Whether that claim meets the standard of liability to state a claim upon which relief may be granted is within the exclusive province of the D.C. District Court, and certainly not any state court. §§247d 6d(d)(1), (e)(1), (e)(5). Moreover, the Supreme Court has instructed the elements of the exclusive federal cause of action do not need to duplicate elements of the preempted state law causes of action in order for complete preemption to apply. *Aetna Health Inc. v. Davila* 542 U.S. 200, 209 (2004).

here uniquely apply federal issues to claims that are pled using solely state tort law. Thus, this case presents a scenario where federal question jurisdiction is indeed based on *Grable*.

Pursuant to the *Grable* doctrine, a federal court can exercise federal question jurisdiction over a state law claim if “a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.” *Gunn v. Minton*, 568 U.S. 251, 258 (2013). Where these requirements are met, jurisdiction in this Court is proper because “there is a ‘serious federal interest in claiming the advantages thought to be inherent in a federal forum,’ which can be vindicated without disrupting Congress’s intended division of labor between state and federal courts.” *Id.* (quoting *Grable*, 545 U.S. at 313-14). The doctrine captures the “commonsense notion” that a federal court ought to hear claims “recognized under state law that nonetheless turn on substantial questions of federal law.” *Grable*, 545 U.S. at 312.

Here, all four prongs of the *Grable* analysis are present. First, a federal issue is “necessarily raised” because the PREP Act, and its implementation to combat COVID-19, involves substantial federal issues in terms of the national, unified response to the pandemic. The Secretary has expressly acknowledged this, citing *Grable*, and stating that “there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of [*Grable*] in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities.” Fourth Amended Declaration, 85 Fed. Reg. at 79197. Likewise, the federal issue is necessarily raised because the PREP Act encompasses any claims that would fall within its definitions, and those claims include the ones asserted here.

The second and third *Grable* prongs are met as well: the applicability of the PREP Act and federal jurisdiction is clearly in dispute here, and whether or not this Court has jurisdiction is a

“substantial question.” A federal issue may be substantial if it “presents a nearly pure issue of law, one that could be settled once and for all and would govern numerous other cases.” *Riseboro Community Partnership v. SunAmerica Housing Fund No. 682*, 401 F.Supp.3d 367, 374 (E.D.N.Y. 2019). The fourth prong, whether exercising federal jurisdiction will disrupt the “federal-state balance,” likewise falls in Defendants’ favor. No matter how one views it, the PREP Act forecloses any review in state court because all claims subject to the Act are either precluded by immunity, or must be federally venued in the District of Columbia. Thus, there is no balance to upset because state courts have no interest here. Likewise, as the Secretary points out in the Fourth Amended Declaration, there is a clear interest in having a unified federal jurisprudential approach to PREP Act claims, as opposed to a piecemeal smattering of state courts interpreting the federal immunity provisions differently around the country. Thus, the Court should retain jurisdiction by applying the *Grable* Doctrine.

III. ALL DEFENDANTS UNDENIABLY JOINED IN AND FILED THIS REMOVAL PETITION AND, THUS, REMOVAL IS NOT PROCEDURALLY DEFECTIVE IN ANY WAY

Plaintiff makes several unavailing arguments in an attempt to circumvent removal, including that removal is procedurally defective because Defendants, Jose Polanco, APN and Kamran Tasharofi, MD did not join in and consent. Nothing could be farther from the truth, and it is difficult to understand the basis for this argument. Here, it is plain from the face of the removal notice that *all* Defendants -- Jose Polanco, APN, Kamran Tasharofi, MD, and Union County Health Care Associates -- are represented by the same law firm, and *all* Defendants filed the removal notice. Thus, *all* defendants clearly joined in and consented to removal in this case. Thus, there is no procedural defect requiring remand as there can be no doubt that *all* defendants are party to the removal of the case to this Court.

CONCLUSION

Plaintiff asserts claims of willful misconduct that fall within the purview of the PREP Act, and the Act provides the exclusive federal cause of action for those claims. Plaintiff's state-law claims are therefore completely preempted. Plaintiff's claims therefore invoke the federal-question jurisdiction and are removeable to this Court. Accordingly, Plaintiff's Motion for Remand should be denied.

Respectfully submitted,

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